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Filed : January 27, 2000

### REMARKS

Claims 35, 85, 96 and 114-118 have been amended. No new claims have been added. Accordingly, elected claims 35-44, 68-77, 79, 85-93, 96, 98, 99 and 112-118 are currently presented for examination.

No new matter has been added to the application. The amendments to claims 35, 85, and 96 constitute relocation of claim language that was added by amendment in a response filed August 5, 2002. In particular, for each of these claims, the phrase "wherein said candidate compound is not previously known to possess the ability to reduce cell proliferation" has been moved from the preamble to the body of the claim. As indicated in the August 5, 2003 response, support for this language can be found in the specification at page 72, lines 10-17 and page 73, lines 20-32. Support for the amendments to claims 114-118 can be found at page 68, lines 2-3.

#### Telephonic Interview

Applicants wish to thank the Examiner for extending the courtesy of a telephonic interview on March 4, 2003. The substance of the interview is reflected in the Interview Summary mailed March 5, 2003 and in the following remarks.

#### Information Disclosure Statement

Applicants note that this response has been filed with an accompanying Information Disclosure Statement that includes Form PTO-1449 listing five references. Copies of the listed references have also been included. Each of these references were recently cited in search reports in connection with patent applications related to the instant case. Applicants believe that none of the cited references affect the patentability of the currently elected claims.

#### Objection to the Specification

The specification of the instant application is objected to because it contains an embedded hyperlink at page 19, line 25. The Examiner has requested that Applicants delete all browser executable code contained within the application.

Applicants have searched the specification and found two instances of browser executable code. The first instance is located at page 19, line 10. The sentence containing this code has

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been deleted. The second instance of browser executable code is located at page 19, line 25. As discussed in the telephonic interview of March 4, 2003, Applicants have replaced this hyperlink with text that teaches the public how to access the intended website using a web browser. Since the amendment causes the text of the hyperlink to be physically separated, the text no longer constitutes browser executable code.

In view of the above amendments, Applicants respectfully request the Examiner to withdraw his objection to the specification.

Claim Rejections Based on 35 U.S.C. § 112, first paragraph

Claims 114-118 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In particular, for each of these claims, the Examiner asserts that the specification lacks a written basis for a limitation which recites that the candidate compound "is present in a natural product extract."

It was agreed in the telephonic interview of March 4, 2003, and stated in the Examiner's Interview Summary of March 5, 2003, that amending claims 114-118 to eliminate the term "extract" would overcome this rejection. As advised, Applicants have amended claims 114-118 to remove the term "extract." The claims now recite that the candidate compound is a natural product. As mentioned above, support for this amendment is present in the specification at page 68, lines 2-3.

In view of the above amendments, Applicants respectfully request that the Examiner withdraw the rejection of Claims 114-118 based on 35 U.S.C. § 112, first paragraph.

Claim Rejections Based on 35 U.S.C. § 112, second paragraph

Claims 35-44, 85-93, 96, 98, 99, 112-114, 117 and 118 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is in response to previous amendments that were made to the preambles of independent claims 35, 85 and 96. In particular, the claims were amended to recite that the candidate compound is not

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previously known to possess the ability to reduce cell proliferation. The Examiner asserts that these amendments cause each of these independent claims, and the claims dependent thereon, to be subject to two possible conflicting interpretations.

As suggested by the Examiner in the telephonic interview of March 4, 2003, Applicants have amended each of independent claims 35, 85 and 96 to move the phrase, "wherein said candidate compound is not previously known to possess the ability to reduce cell proliferation" from the preamble to the body of the claim. It was stated in the Examiner's Interview Summary of March 5, 2003, that moving this phrase from the preamble to the body of the claim would overcome the rejection based on 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the Examiner withdraw his rejection of claims 35-44, 85-93, 96, 98, 99, 112-114, 117 and 118 based on 35 U.S.C. § 112, second paragraph.

Claim Rejections Based on 35 U.S.C. § 102(b)

Claims 68, 79, 96, 98, 112, 113, 115, 116 and 118 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the disclosure of Gucev *et al.* (1996) Cancer Research **56**:1545. In particular, the Examiner asserts that Gucev *et al.* disclose a number of tests wherein antisense or sense oligonucleotides are added to cells along with candidate compounds for interaction with IGFBP-3 such as retinoic acid or TGF- $\beta$ 2. The Examiner goes on to assert that Gucev *et al.* determine the effect of the candidate compounds compared between antisense and sense inhibition.

In the interview of March 4, 2003, Applicants' representatives pointed out that several of the steps recited in Claims 68, 79 and the claims dependent thereon, were not disclosed in Gucev *et al.* In particular, among other steps recited in the claims and not disclosed in the cited reference, Gucev *et al.* does not disclose contacting a microorganism with a proliferation-inhibiting amount of inhibitory nucleic acid. As agreed in the telephonic interview of March 4, 2003 and stated in the Examiner's Interview Summary of March 5, 2003, Gucev *et al.* does not disclose every element of independent claims 68, 79 or the claims dependent thereon.

Independent claim 96 is not anticipated by the disclosure of Gucev *et al.* because, among other steps recited in the claims and not disclosed in the cited reference, the pending claims recite that the candidate compound is not previously known to possess the ability to reduce cell

proliferation. As acknowledged in the Examiner's Office Action, Gucev *et al.* discloses the use of two compounds, retinoic acid and TGF- $\beta$ 2 to inhibit proliferation; however, each of these compounds were previously known to have this effect (see Gucev, *et al.* at page 1545, column 2, paragraph 2). Accordingly, Gucev *et al.* does not disclose every element of claim 96 or the claims dependent thereon.

In view of the above remarks, independent claims 68, 79 and 96, as well as claims dependent thereon, are not anticipated by Gucev, *et al.*. Accordingly, Applicants request that the Examiner withdraw the rejection of claims 68, 79, 96, 98, 112, 113, 115, 116 and 118 based on 35 U.S.C. § 102(b).

#### Examination of Additional Species

Applicants note that the Examiner issued a Restriction Requirement on June 26, 2001 (Paper Number 8), which, among other things, contained an election of species requirement. In response to the Restriction Requirement Applicants elected Group IX comprising claims 35-46, 68-77, 79-83, 85-94, and 96-101.

With respect to the claims in Group IX, the Examiner divided the Group into the following four species: (A) inhibiting polypeptide or gene product activity; (B) reducing polypeptide gene product amount; (C) inhibiting nucleic acid activity; and (D) reducing the amount of encoding nucleic acid. The Examiner further noted that claims 35-44, 68-77, 79, 85-94, 96, 98 and 99 were generic.

In response to the election of species, Applicants elected species A, "inhibiting polypeptide or gene product activity," with traverse. Specifically, Applicants argued that the species, "inhibiting polypeptide or gene product activity," includes each of the other species (species B-D) set out by the Examiner. In particular, the Applicants maintained and continue to maintain that inhibiting polypeptide or gene product activity encompasses each of the other species. For example, as noted in the Response to Restriction Requirement, Applicants continue to maintain that the activity of a polypeptide will be inhibited if one reduces the amount of a polypeptide gene product (species B), inhibits the activity of a nucleic acid encoding the gene product (species C), or reduces the amount of nucleic acid encoding the gene product (species D). The Examiner did not agree with the traversal of the election of species, and accordingly a

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number of dependent claims (claims 45, 46, 80-83 and 97), which were present in the elected claim Group, were withdrawn from consideration because they were allegedly drawn to a nonelected species. Additionally, a claim added by subsequent amendment, claim 111, was alleged to read on a nonelected species, and thus, withdrawn by the Examiner.

According to M.P.E.P. § 809.04, upon allowance of a generic claim, the Applicants are entitled to have such withdrawn claims considered. Thus, if the Examiner finds the generic claims of the elected claim Group allowable, as acknowledged in the Interview Summary, Applicants respectfully request that the Examiner consider the claims, including previously withdrawn claims, with respect to each of the remaining species (species B-D) as required under M.P.E.P. § 809.04. Applicants further respectfully request that in accordance with M.P.E.P. § 809.02(c), should the Examiner find the generic claims allowable, the Notice of Allowance should indicate withdrawal of the restriction requirement as to the species fully embraced by the generic claims. If the Examiner has any questions or concerns regarding the foregoing issue, he is cordially invited to contact the undersigned via telephone for clarification.

### CONCLUSION

Applicants believe that all outstanding issues in this case have been resolved and that the present claims are in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite the resolution of such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,  
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1/27/00

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